5. 510(k) Summary

K061676

Submitter: Frank B. Freedman, Ph.D.*
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* on behalf of Uroan 21 Electromedicine

DEC 2 7 2006

Contact Person: Frank B. Freedman
Alliancz Medical Consultants, Inc.

Device Common Name: Penile rigidity and/or tumescence monitor

Device Trade Name: Uroan Model DIR-4U Rigidometer

Device Classification Name: Not classified

Predicate Devices: Uroan Model DIR-101C Rigidometer (K000194)

Device Description
The DIR-4U Rigidometer consists of an instrument and attached sensor that measures penile axial rigidity. It has been designed, so that men can use this instrument in the privacy of their homes to measure their penile axial rigidity.

Indications for Use
The Uroan DIR-4U Rigidometer measures penile axial rigidity.

Comparison to Predicate Devices
The Uroan Model DIR-4U Rigidometer is substantially equivalent to Uroan Model DIR-101C Rigidometer. It uses the same sensor and principle of operation to obtain these measurements. The DIR-4U uses indicator lights to indicate the measured axial rigidity. DIR-101C axial rigidity measurements are displayed on a computer screen. Unlike the DIR-101C, the DIR-4U does not measure glans temperature, estimate relative intracavernosal pressure or tabulate or store measurements.

Supporting Information
Bench, biocompatibility and clinical testing supported the substantial equivalency of the DIR-4U Rigidometer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

DEC 27 2006

Uroan 21 Electromedicine
c/o Frank B. Freedman, Ph.D.
Alliancz Medical Consultants, Inc.
2530 Pennsylvania Avenue South
ST LOUIS PARK MN 55426

Re: K061676
Trade/Device Name: Uroan DIR-4U Rigidometer
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LIL
Dated: November 24, 2006
Received: November 27, 2006

Dear Dr. Freedman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

K061676

510(k) Number (if known): (K061676)

Device Name: DIR-4U Rigidometer

Indications For Use: The Uroan DIR-4U Rigidometer measures penile axial rigidity.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061676